IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bernard Corfe and Hari Chirakkal
Application No. 10/581,702
Filed: November 3, 2006
Confirmation No. 3624
For: GENE SCREEN
Examiner: Not yet assigned
Art Unit: Not yet assigned
Attorney Reference No. 5585-75901-01

FILED VIA EFS
ON DECEMBER 20, 2006

REQUEST FOR CORRECTED OFFICIAL FILING RECEIPT

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Applicants have received the official Filing Receipt for the application referenced above, a copy of which (with requested correction handwritten thereon) is attached as Exhibit A.

The following error appears on the Filing Receipt:

ITEM IN ERROR	CORRECT INFORMATION
Foreign Applications: United Kingdom 0329048.4 12/04/2003	Foreign Applications: United Kingdom 0328048.4 12/04/2003

Attached as Exhibit B is a copy of the cover page of the published PCT application, which has the correct United Kingdom application number. Attached as Exhibit C is a copy of the Preliminary Amendment filed on June 2, 2006, which has the correct United Kingdom application number. Attached as Exhibit D is a copy of the signed Combined Declaration and Power of Attorney filed on November 3, 2006, which has the correct United Kingdom application number.

Applicants request that the identified error be corrected and that a new official Filing Receipt be issued.

Please call the undersigned if any further information is required.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

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By _____
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cc: Docketing

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/581,702	11/03/2006	1614	1565	5585-75901-01	6	36	4

CONFIRMATION NO. 3624

FILING RECEIPT

24197
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PORTLAND, OR97204

Date Mailed: 12/06/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Bernard Corfe, Stockport, UNITED KINGDOM;
Hari Chirakkal, Sheffield, UNITED KINGDOM;

Power of Attorney: The patent practitioners associated with Customer Number 24197

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/GB04/05078 12/03/2004

Foreign Applications

UNITED KINGDOM 0329048.4 12/04/2003 (should be 0328048.4)

If Required, Foreign Filing License Granted: 12/04/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/581,702**

Projected Publication Date: 03/15/2007

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Gene screen

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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WO 2005/054507 A2

(54) Title: GENE SCREEN

(57) Abstract: We describe a method for the identification of genes which show regulated expression in response to carbon source utilisation, typically genes associated with the initiation and/or promotion of cell transformation from a non-cancerous to a cancerous phenotype, typically of cells found in the colon; the use of these genes in diagnostic assays and as targets for the development of chemotherapeutic drugs and agents identified by said assay.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
Bernard Corfe and Hari Chirakkal
Application No. Currently unknown
Filed: Herewith
Confirmation No. Currently unknown
For: GENE SCREEN
Examiner: Not yet assigned
Art Unit: Not yet assigned
Attorney Reference No. 5585-75901-01

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PRELIMINARY AMENDMENT

Prior to calculation of the fees and examination of the above-identified patent application, please amend the application as follows to comply with national stage requirements.

Amendments to the Specification begin on page 2.

Amendments to the Claims are reflected in the listing of claims, which begins on page 3.

Remarks begin on page 10.

An **Abstract** is attached as a separate page at the end of this document.

Amendments to the Specification

Please add the following new paragraphs after the after the title:

CROSS REFERENCE TO RELATED APPLICATIONS

This is the U.S. National Stage of International Application No. PCT/GB2004/005078, filed December 3, 2004 (published in English under PCT Article 21(2)), which in turn claims the benefit of Great Britain Application no. 0328048.4, filed December 4, 2003.

Please insert the Abstract, submitted herewith on a separate page, as page 260 at the end of the application.

Please include the enclosed sequence listing (277 pages), which is submitted on CD-ROM, at the end of the application.

Amendments to the Claims

1. (Currently Amended) A method to screen for nucleic acid molecules which show altered expression in an isolated first cell sample comprising:

comparing ~~the~~ gene expression profiles between said first cell sample with a second reference cell sample wherein said first cell sample has been grown in the presence of the carbon source butyrate, or a related carbon source from which butyrate is derived, either directly or indirectly, and

comparing ~~said~~ the expression profile in the first cell sample with the expression profile in said second reference cell sample which has not been grown in the presence of butyrate, or said related carbon source.

2. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 1 wherein said screen for nucleic acid molecules comprises ~~the steps of~~:

i) providing

a) a cell growth preparation comprising a first cell sample derived from at least one region of the colon; cell growth media; and a carbon source wherein said carbon source is butyrate; and

b) a cell growth preparation comprising a second cell sample derived from an equivalent region of the colon; cell growth media; and a carbon source which is not butyrate;

ii) extracting nucleic acid from said first and second cell samples; and

iii) comparing the gene expression profile in said first cell sample with the gene expression profile in said second cell sample.

3. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 1 ~~or 2~~ wherein said first and second cell samples are derived from the ascending colon, transverse colon, descending colon, sigmoid region of the colon, or rectal region of the colon.

4. – 7. (Canceled)

8. (Currently Amended) [[A]] The method ~~according to any~~ of ~~Claims~~ claim 1[[-7]] wherein said first and second cell samples comprise epithelial cells.

9. (Currently Amended) [[A]] The method ~~according to any~~ of ~~Claims~~ claim 1[[-8]] wherein said carbon source which is not butyrate is glucose.

10. (Currently Amended) [[A]] The method ~~according to any~~ of ~~Claims~~ claim 1[[-9]] wherein said nucleic acid molecule which shows altered expression is selected from the group as represented by the nucleic acid sequences shown in Table 1, or nucleic acid molecules which hybridise to the sequences presented Table 1.

11. (Original) A method for the detection of at least one nucleic acid molecule associated with the initiation and/or progression of colorectal cancer, in an animal, comprising the steps of:

i) providing a biological sample comprising at least one cell to be tested;

ii) contacting said sample with a ligand which binds at least one nucleic acid molecule as represented by the nucleic acid sequence selected from the group consisting of:

a) a nucleic acid molecule as represented by the nucleic acid sequence as shown in Table 1;

b) a nucleic acid molecule which hybridises to nucleic acid molecules as defined in (a);

c) a nucleic acid molecule that is degenerate as a consequence of the genetic code to the nucleic acid molecule represented in (a) and (b);

iii) detecting the presence of at least one nucleic acid molecule in said sample.

12. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 11 wherein said colorectal cancer is adenocarcinoma.

13. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 11 ~~or 12~~ wherein said ligand is a nucleic acid molecule adapted to anneal to said nucleic acid molecule which is indicative of colorectal cancer.

14. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 13 wherein said method is a polymerase chain reaction method.

15. (Original) A method for the detection of at least one polypeptide associated with the initiation and/or progression of colorectal cancer, in an animal, comprising the steps of:

i) providing a biological sample comprising at least one cell to be tested;

ii) contacting said sample with at least one ligand which ligand specifically binds at least one polypeptide encoded by a nucleic acid molecule as represented by the nucleic acid sequence shown in Table 1, or a variant polypeptide comprising an amino acid sequence which varies by the addition, deletion or substitution of at least one amino acid residue; and

iii) detecting the presence of at least one polypeptide in said sample.

16. (Currently Amended) [[A]] The method ~~according to any of Claims~~ claim 11[[-15]] wherein said animal is human.

17. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 15 ~~or 16~~ wherein said ligand is an antibody.

18. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 17 wherein said antibody is a monoclonal antibody, or ~~at least the~~ an effective binding part thereof.

19. (Canceled)

20. (Original) A method to screen for agents which modulate the activity of at least one gene associated with the initiation and/or progression of colorectal cancer comprising the steps of:

i) forming a preparation comprising at least one polypeptide wherein said polypeptide is encoded by a nucleic acid molecule as represented by the nucleic acid sequence as shown in Table 1, or a variant polypeptide comprising an amino acid sequence which varies by the addition, deletion or substitution of at least one amino acid residue as represented by the amino acid sequences shown in Table 1, and at least one agent to be tested; and

ii) determining the activity of said agent with respect to activity of said polypeptide.

21. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 20 wherein said polypeptide is expressed by a cell wherein said cell is transformed or transfected with said nucleic acid molecule.

22. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 21 wherein said nucleic acid molecule is part of a vector adapted for recombinant expression of said nucleic acid molecule.

23. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 22 wherein said vector comprises ~~is provided with~~ a promoter which enables the expression of said nucleic acid molecule to be regulated.

24. (Currently Amended) [[A]] The method ~~according to any~~ of ~~Claims~~ claim 21[[-23]] wherein said cell is derived from the colon.

25. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 24 wherein said cell is an epithelial cell.

26. (Currently Amended) [[A]] The method ~~according to any~~ of ~~Claims~~ claim 20[[-25]] wherein said agent is an antibody.

27. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 26 wherein said antibody is a monoclonal antibody or modified monoclonal antibody, or at least the effective binding part thereof.

28. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 27 wherein said effective binding part ~~fragment~~ is a Fab fragment.

29. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 28 wherein said antibody is selected from the group consisting of: $F(ab')_2$, Fab, Fv and Fd fragments; and antibodies comprising CDR3 regions.

30. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 26 wherein said antibody is a humanized antibody.

31. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 26 wherein said antibody is a chimeric antibody.

32. (Currently Amended) [[A]] The method ~~according to any~~ of ~~Claims~~ claim 20[[-25]] wherein said agent is a polypeptide, peptide, or nucleic acid molecule.

33. – 34. (Canceled)

35. (Currently Amended) [[A]] The method according to ~~Claim~~ claim [[34]]32 wherein said nucleic acid molecule is an aptamer, an inhibitory RNA molecule, or an antisense nucleic acid molecule.

36. (Canceled)

37. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 36 wherein said inhibitory RNA is encoded by a transcription cassette comprising a nucleic acid molecule, or part thereof, wherein said molecule is selected from the group consisting of:

i) a nucleic acid molecule represented by the nucleic acid sequence shown in Table 1 ;

ii) a nucleic acid molecule which hybridises to the sequence in (i) above and which encodes a polypeptide which initiates or promotes transformation of colon cells; or

iii) a nucleic acid molecule which is degenerate because of the genetic code to the sequences defined in (i) and (ii) above, wherein said cassette is adapted such that both sense and antisense nucleic acid molecules are transcribed from said cassette.

38. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 37 wherein said cassette is provided with at least two promoters adapted to transcribe both sense and antisense strands of said nucleic acid molecule.

39. (Currently Amended) [[A]] The method according to ~~Claim~~ claim 37 wherein said cassette comprises a nucleic acid molecule wherein said molecule comprises a first part linked to a second part wherein said first and second parts are complementary over at least ~~part~~ a portion of their sequence and further wherein transcription of said nucleic acid molecule produces an RNA molecule which forms a double stranded region by complementary base pairing of said first and second parts.

40. (Canceled)

41. (Currently Amended) A pharmaceutical composition comprising an~~An~~ antibody or effective binding part thereof, identified by the method ~~according to any~~ of ~~Claims~~ claim 26[[-31 for use as a pharmaceutical]].

42. (Currently Amended) A pharmaceutical composition comprising a [[A]]polypeptide identified by the method according to ~~Claim~~ claim 32 ~~for use as a pharmaceutical~~.

43. (Canceled)

44. (Currently Amended) A pharmaceutical composition comprising a [[A]] nucleic acid molecule identified by the method according to ~~Claim~~ claim 32~~34 for use as a pharmaceutical~~.

45. (Currently Amended) The pharmaceutical composition of ~~Use according to Claim~~ claim 44 wherein said nucleic acid molecule is an aptamer, inhibitor RNA, or an antisense nucleic acid molecule.

46. – 47. (Canceled)

48. (Currently Amended) The pharmaceutical composition of ~~Use according to any of Claims~~ claim 41[[-47]] wherein said pharmaceutical composition further comprises a [[a]]diluent, carrier or excipient.

Remarks

Claims 1-48 were pending. By this amendment, claims 4-7, 19, 33-34, 36, 40, 43, and 46-47 are cancelled. No claims are added. Therefore, claims 1-3, 8-18, 20-32, 35, 37-39, 41-42, 44-45, and 48 are pending.

By this amendment, the specification was amended to incorporate Applicants' claim of priority, and to include a sequence listing and an abstract. The claims were amended to comply with U.S. practice, for example the removal of multiple dependencies and correction of antecedent basis.

Support for the amendments can be found throughout the specification, for example:

claim 3: original claims 4-7.

claim 32: original claims 33-34

claim 35: original claims 36 and 40.

claim 45: original claims 46 and 47.

No new matter is added by this amendment. No amendments made herein were to distinguish prior art. If there are any questions regarding this amendment, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By _____
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COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled GENE SCREEN, the specification of which

☐ is attached hereto.

☒ was filed on 02 June 2006 as United States Patent Application No 10/581,702

☒ was described and claimed in PCT International Application No PCT/GB2004/005078, filed on 03 December 2004, and as amended under PCT Articles 19 on _____ (if applicable).

☐ and was amended on _____ (if applicable)

☐ with amendments through _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above

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Number	Country	Day/Month/Year Filed	Claim Priority?	
0328048 4	Great Britain	04 December 2003	☒ Yes	☐ No

I hereby claim the benefit under 35 U S C § 119(e) of any United States provisional application(s) listed below:

Application Number	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) or § 365(c) of any PCT international application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Number	Filing Date	Status: patented, pending, abandoned

I hereby appoint the practitioners associated with the customer number provided below to prosecute this application, to file a corresponding international application, and to transact all business in the Patent and Trademark Office connected therewith:

Customer Number 24197

I hereby grant the law firm of Klarquist Sparkman, LLP, the power to insert on this Combined Declaration and Power of Attorney any further information which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for submitting this document

Address all telephone calls to Sheree Lynn Rybak, Ph.D. at telephone number (503) 595-5300

Address all correspondence to the address associated with **Customer Number 24197**, which address is:

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121 S.W. Salmon Street, Suite 1600
Portland, OR 97204

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon

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